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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,800	10/18/2006	Paul Douglas Clarke	PAC/23581 US (4137-01100)	1534

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EXAMINER	
BROOKS, KRISTIE LATRICE	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,800	CLARKE, PAUL DOUGLAS	
	Examiner	Art Unit	
	KRISTIE L. BROOKS	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/24/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 23-42 are pending.

Specification

2. The abstract of the disclosure is objected to because it is not descriptive enough of the invention. The abstract should be between 50-150 words in length. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112 1st

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 23-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for destroying, inactivating, or inhibiting the growth of some viruses such as influenza (i.e. A/Sydney/5/97), Herpes Simplex Virus-1, and Urbani SARS does not reasonably provide enablement for destroying, inactivating, or inhibiting the growth of **any and all** viruses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

Scope or breadth of the claims

The scope of the claims is drawn to a method of using p-menthane-3,8-diol (PMD) to destroy, inactivate or inhibit growth or reproduction of any virus. Hence, the scope is broad.

Nature of the invention

The nature of the invention is directed to a method of using p-menthane-3,8-diol (PMD) to destroy, inactivate or inhibit growth or reproduction of any virus.

State of, or the amount of knowledge in, the prior art

There are many proposed treatments for viruses. Most treatments have distinct drugs that are used to treat only certain viruses. Such as interferon-α used to treat hepatitis and anti-retroviral drugs used to treat HIV-infection(Taiwo, Abstract, Antiretroviral treatment: current approach and future prospects, *African Journal of Medical Medicines and Science*, 35 Suppl: 1-11, 2006; Safren et al., Abstract, Strategies for primary HIV prevention that target behavioral change, *Clinical of Infectious diseases*, 45 Suppl 4:S300-307, 2007; Krastev, The "return "of hepatitis B, *World Journal of Gastroenterology*, 12(44):7081-7086, 2006)..

Level or degree of predictability, or a lack thereof, in the art

Claim 1 is directed to a method of using p-menthane-3,8-diol (PMD) to destroy, inactivate or inhibit growth or reproduction of **any** virus. There is a seemingly infinite number of species of viruses encompassed by the term "virus." Many viruses use different distinct drugs designed specifically to target the viruses' mechanism to produce disease, such as interferon-α for Hepatitis B or anti-retroviral agents for HIV-infections. There is no known drug capable of treating all viruses and thus there is a high level of unpredictability as to whether p-menthane-3,8-diol is capable of destroying, inactivating or inhibiting growth or reproduction of **all** viruses.

Amount of guidance or direction provided by the inventor

The specification provides guidance on destroying, inactivating or inhibiting growth or reproduction of viruses such as A/Sydney/5/97, Herpes Simplex Virus-1, or

Urbani SARS using PMD. However, the specification fails to provide guidance or direction on destroying, inactivating or inhibiting growth or reproduction of any other virus.

Presence or absence of working examples

The specification provides examples of the virucidal activity of PMD on only three viruses, i.e. A/Sydney/5/97, Herpes Simplex Virus-1, or Urbani SARS.

The specification fails to provide scientific data and working embodiments with respect to destroying, inactivating or inhibiting growth or reproduction of viruses other than A/Sydney/5/97, Herpes Simplex Virus-1, or Urbani SARS.

Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

One of ordinary skill in the art would have to conduct a myriad of experimentation to determine whether PMD is effective at treating viruses other than A/Sydney/5/97, Herpes Simplex Virus-1, or Urbani SARS. Viruses have different mechanisms by which they can produce disease and separate planning is crucial in developing an effective treatment that can target the specific mechanism for that specific disease. One of ordinary skill would have to conduct series of trials to determine the mechanism by which the virus produces disease and determine whether PMD is effective in vivo, in vitro, etc, for each distinct virus. Since Applicant has only shown the virucidal activity of PMD on three viruses out of the seemingly infinite number of viruses and no guidance

was provided for any other virus, one of ordinary skill in the art would be required to conduct an undue amount of experimentation.

For the foregoing reasons, Applicant is not enabled for destroying, inactivating or inhibiting growth or reproduction of **all** viruses using PMD.

Claim Rejections - 35 USC § 112 2nd

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 23-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites "A method comprising using p-methane-3,8-diol (PMD) to destroy, inactivate growth or reproduction of a virus." The claim does not provide an active method step to distinguish the prior art over the instant invention. Further, the term "using" does not provide adequate description of the intended purpose of p-methane-3,8-diol (PMD).

For purposes of Examination, the Examiner interprets the claim to read as a method of destroying, inactivating the growth or reproduction of a virus comprising administering p-methane-3,8-diol (PMD) to a surface.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 23-39 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke (WO 01/05226) in view of Vail, III et al. (US 2004/0009245).

Applicant claims a method of destroying, inactivating the growth or reproduction of a virus comprising administering p-methane-3,8-diol (PMD).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Clarke teaches p-methane-3,8-diol (PMD) has antiseptic, antibiotic, bactericidal and fungicidal properties (see the abstract). The PMD can derived from a natural

source, preferably the lemon eucalyptus plant (see page 2 paragraph 2). The PMD be extracted in pure form, or a crude extract derived from the lemon eucalyptus plant (also called Eucalyptus Citriodora) (see page 2 paragraphs 2-3). The composition of the invention can comprise PMD and a carrier (see page 2 paragraph 7). The PMD can be used to sanitize surfaces such as a skin surface (i.e. hand, open wound, etc), nasal passage, glove, apparatus, etc (see page 4 paragraph 2 and claims 17 and 20-23). The PMD can be impregnated into household objects, medicine, detergents, cleansers, etc. (see page 3, paragraph 6 and page 5, paragraph 2-6). The PMD composition can be formulated as a throat lozenge, shampoo, skin spray, nasal spray, wound irrigation, cream for nasal administration and as a spray (see page 3 paragraph 6, page 4 paragraph 1 and claim 12).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Clark does not teach the antiviral properties of p-methane-3,8-diol (PMD). Further, Clark does not teach the use of PMD to treat viruses. These deficiencies are cured by the teachings of Vail, III et al.

Vail, III et al. teach concentrated antiseptic botanical essential oils such as Eucalyptus citriodora have antiviral, antibacterial, and antifungal properties (see the abstract). The concentrated vapors from the essential oils can be used to treat viruses

such as influenza, herpes simplex virus, etc., which can cause Severe Acute Respiratory Syndrome (SARS), (see the abstract, page 21 paragraphs 519, and 525-527).

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use PMD to treat viruses.

One of ordinary skill in the art would have been motivated to do this because Clark suggests PMD, which is derived from lemon eucalyptus (or Eucalyptus Citriodora), has antiseptic properties and can be applied to surfaces. Although Clark does not teach treating viruses with PMD it would have been obvious to one or ordinary skill in the art to treat viruses with PMD because PMD is derived from Eucalyptus Citriodora (lemon eucalyptus), which is a known antiseptic with antiviral properties as taught by Vail, III et al. Thus, since PMD is derived from a known antiseptic essential oil with antiviral properties for the treatment of viruses, one of ordinary skill can reasonably expect PMD to be an effective antiseptic capable of treating viruses. Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

9. Claims 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke (WO 01/05226) in view of Vail, III et al. (US 2004/0009245) further in view of Lemelson (US 4,856,509).

Applicant claims a method of destroying, inactivating the growth or reproduction of a virus comprising administering p-methane-3,8-diol (PMD).

Determination of the scope and content of the prior art

(MPEP 2141.01)

The disclosure of Clarke is et forth above. Specifically, Clarke teaches p-methane-3,8-diol (PMD) composition that has antiseptic, antibiotic, bactericidal and fungicidal properties.

Vail, III et al. teach concentrated antiseptic botanical essential oils such as Eucalyptus citriodora have antiviral, antibacterial, and antifungal properties (see the abstract). The concentrated vapors from the essential oils can be used to treat viruses such as influenza, herpes simplex virus, etc., which can cause Severe Acute Respiratory Syndrome (SARS), (see the abstract, page 21 paragraphs 519, and 525-527).

Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)

Clark and Vail, III et al. do not teach the application of PMD to a face mask. This deficiency is cured by the teaching of Lemelson.

Lemelson teaches improved face masks, for use in preventing the spread of disease such as colds, influenza, or viral infections, wherein a portion of the mask contains a disease or viral destroying chemical or biological agent (see the abstract and column 1 lines 35-40, column 2 lines 6-10). The mask can be provided with a filter element with a removable capping sheet that contains the disease or viral destroying chemical or biological agent (see column 3 lines 10-44 and column 8 lines 14-23). The releasable medication may be in the form of an antibiotic, antiseptic, antibacterial or virus destroying medication (see column 9 lines 4-9).

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a face mask containing PMD.

One of ordinary skill in the art would have been motivated to do this because Lemelson suggest the use of face masks containing viral destroying agents. Although Clark and Vail et al. do not teach the use of face masks containing PMD, it would have been obvious to one of ordinary skill in the art to use face masks containing PMD because it is already known in the art to use face masks impregnated with viral

destroying agents to prevent the spread of disease as suggested by Lemelson. Thus, one of ordinary skill would use a face mask containing PMD to prevent the spread of diseases or viral infections to other individuals. Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 23-25,28,39, and 42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1-6 and 9 of U.S. Patent No. 7,189,421.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a method of destroying, inactivating the growth or reproduction of a virus comprising administering p-methane-3,8-diol (PMD).

Claims 1-6 and 9 of U.S. Patent 7,189,421 are drawn to a method of treating a fungal infection in a patient comprising administering PMD to the patient.

The instant claims differ from the cited patent by the method of use. However, the method of treating a fungal infection in the cited patent is not conclusive to a population of patients with just fungal infections, and thus is not patentably distinct from the instant claims because by administering the PMD to a patient, the patient would implicitly be destroying or inactivating the virus or treating a fungal infection. Therefore, both applications are directed to similar subject matter wherein they each administering PMD.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristie L. Brooks whose telephone number is (571) 272-9072. The examiner can normally be reached on M-F 8:30am-6:00pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on (571) 272-0646. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KB

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616